GOOD SENSE COMPLETE- famotidine, magnesium hydroxide and calcium carbonate tablet, chewable

L Perrigo Company

Perrigo Complete Drug Facts

Active ingredient (in each chewable tablet)

Famotidine 10 mg

Calcium carbonate 800 mg

Magnesium hydroxide 165 mg

Purpose

Acid reducer

Antacid

Uses

relieves heartburn associated with acid indigestion and sour stomach

Warnings

Allergy alert: Do not use if you are allergic to famotidine or other acid reducers

Do not use

- if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
- with other acid reducers

Ask a doctor before use if you have

- had heartburn over 3 months. This may be a sign of a more serious condition.
- heartburn with lightheadedness, sweating, or dizziness
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent chest pain
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain

Ask a doctor or pharmacist before use if you are

presently taking a prescription drug. Antacids may interact with certain prescription drugs.

Stop use and ask a doctor if

- your heartburn continues or worsens
- you need to take this product for more than 14 days

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

- adults and children 12 years and over:
- do not swallow tablet whole: chew completely
- to relieve symptoms, chew 1 tablet before swallowing
- do not use more than 2 chewable tablets in 24 hours
- children under 12 years: ask a doctor

Other information

- each tablet contains: calcium 320 mg; magnesium 70 mg
- Phenylketonurics: Contains phenylalanine 2.2 mg per tablet
- read the directions and warnings before use
- read the bottle label. It contains important information.
- store at 20-25°C (68-77°F)
- protect from moisture

Inactive ingredients

anhydrous lactose, artificial berry flavor, aspartame, D&C red no. 7 calcium lake, dextrates, FD&C blue no. 1 aluminum lake, FD&C red no. 40 aluminum lake, glyceryl monostearate, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyacrylate dispersion, polysorbate 80, povidone, pregelatinized starch, sodium starch glycolate, talc

Questions or comments?

1-800-719-9260

Principal Display Panel

Dual Action

Complete

Famotidine 10 mg/Calcium Carbonate 800 mg

Magnesium Hydroxide 165 mg Tablets

Acid Reducer plus Antacid

Just One Tablet! Relieves Heartburn Due to Acid Indigestion

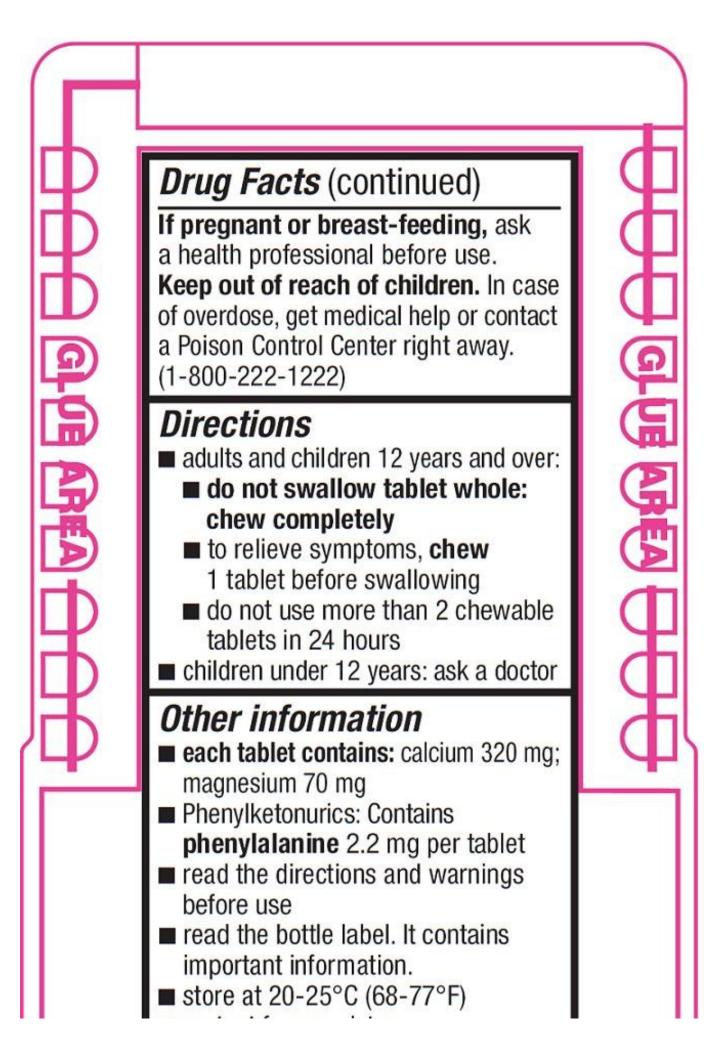
Actual Size

Berry Flavor

Compare to active ingredients of Pepcid Complete®



Complete Label Image 1



protect from moisture

Inactive ingredients anhydrous lactose, artificial berry flavor, aspartame, D&C red no. 7 calcium lake, dextrates, FD&C blue no. 1 aluminum lake, FD&C red no. 40 aluminum lake, glyceryl monostearate, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyacrylate dispersion, polysorbate 80, povidone, pregelatinized starch, sodium starch glycolate, talc

Complete Label Image 2

GOOD SENSE COMPLETE

famotidine, calcium carbonate and magnesium hydroxide tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0113-0321
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
FAMO TIDINE (UNII: 5QZO15J2Z8) (FAMOTIDINE - UNII:5QZO15J2Z8)	FAMOTIDINE	10 mg	
MAGNESIUM HYDRO XIDE (UNII: NBZ3QY004S) (MAGNESIUM HYDRO XIDE - UNII:NBZ3QY004S)	MAGNESIUM HYDRO XIDE	165 mg	
CALCIUM CARBONATE (UNII: H0G9379FGK) (CARBONATE ION - UNII:7UJQ5OPE7D)	CALCIUM CARBONATE	800 mg	

Inactive Ingredients		
Ingredient Name	Strength	
ASPARTAME (UNII: Z0H242BBR1)		
D&C RED NO. 7 (UNII: ECW0LZ41X8)		
DEXTRATES (UNII: G263MI44RU)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)		
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
ANHYDRO US LACTO SE (UNII: 3S Y5LH9 PMK)		
LACTO SE MO NO HYDRATE (UNII: EWQ57Q815X)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
POLYSORBATE 80 (UNII: 6OZP39ZG8H)		

	PO VIDO NE (UNII: FZ989GH94E)	
ı	TALC (UNII: 7SEV7J4R1U)	۱
ı	SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	ı

Product Characte	roduct Characteristics		
Color	PINK (mottled)	Score	no score
Shape	ROUND (bi-layered)	Size	17mm
Flavor	BERRY	Imprint Code	L321
Contains			

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:0113-0321-63	25 in 1 BOTTLE			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077355	08/05/2008	

Labeler - L Perrigo Company (006013346)

Revised: 5/2009 L Perrigo Company